

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Applicants thank the Examiner for acknowledging that claims 23-27, 31, 32, and 36-51 are allowed and that claims 19 and 20 are objected to for depending from a rejected claim.

Applicants also thank the Examiner for withdrawing his previous rejections for claims 16 and 36 under 35 U.S.C. § 103(a) as being obvious over European Patent No. EP 0 257 915 to Boyes *et al.* ("Boyes") and of claim 22 over Boyes in view of U.S. Patent No. 4,866,051 to Hunt *et al.* ("Hunt").

**Request for Withdrawal of Finality of Rejection and
Refund of fees for Request for Continued Examination**

In the current Office Action, the Examiner finally rejected claims 16, 18, 22, and 52-54 under 35 U.S.C. §103(a) as being obvious in view of U.S. Patent No. 6,132,766 to Sankaram *et al.* ("Sankaram"). Applicants respectfully point out that the indication that this is a "final" rejection appears to be incorrect.

Section 706.07(a) of the MPEP states that "under present practice, second or subsequent actions on the merits shall be final, *except where the Examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement* filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." (emphasis added)

Independent claims 16 and 22 were amended in the previous Amendment filed July 25, 2007 and the Substitute Amendment filed July 26, 2007, to specify that the material that is used

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to form the microparticles is selected from alginate, chitosan, hydrophilic or hydrophobic proteins, and lipids. Prior to this amendment, claims 16 and 22 specified a broad range of materials, namely proteins, polymers of mixed amino acids, polysaccharides, lipids and surface active agents, as the materials that could be used to form the microparticles. Further, alginate and chitosan were specifically mentioned in prior dependent claim 21 (which depended from claim 16). Thus the amendments to claims 16 and 22, which narrowed the scope of the claims and incorporated materials that were previously listed in dependent claims, should not have caused the new rejection for these claims.

The amendment to dependent claim 18 was merely to correct antecedent basis by replacing the term “microparticle” with “microparticles”. This amendment did not change the scope of claim 18.). Thus the amendment to claims 18 should not have caused the new rejection for this claim.

New dependent claim 52-54, which depend from claim 16 directly and indirectly, were added. These claims merely further define the drug in the microparticles. Since claim 16 previously indicated that any drug could be present in the microparticles, new claims 52-54, the addition of new claims 52-54 should not have caused a new rejection for the claims.

Further, the new rejection of claims 16, 18, 22, and 52-54 was not based on information submitted in an information disclosure statement. Accordingly, the Examiner’s final rejection of claims 16, 18, 22, and 52-54 is improper.

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Applicants respectfully request withdrawal of the Finality of the Office Action mailed October 1, 2007. And reimbursement of the fee for the Request for Continued Examination (RCE) submitted with this Amendment and Response.

Rejection Under 35 U.S.C. § 103

16, 18, 22, and 52-54 under 35 U.S.C. §103(a) as being obvious in view of U.S. Patent No. 6,132,766 to Sankaram *et al.* ("Sankaram"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Analysis

Sankaram discloses compositions of multivesicular liposomes for drug delivery (see col. 1, lines 18-20). Sankaram defines "multivesicular liposomes" as meaning "man-made microscopic lipid vesicles enclosed multiple non-concentric aqueous chambers formed by internal membranes." (col. 3, lines 49- 52). As acknowledged by the Examiner, Sankaram discloses forming its liposomes using lipids. (Office Action at page 3, lines 13-14, *citing* Sankaram at col. 5, lines 3-20). No other material listed in independent claims 16 and 22 is included in Sankaram's microparticles.

Although Applicants believe that claims 16, 18, 22 and 52-54 as presented in the Amendments filed on July 25, 2007 and July 26, 2007 are non-obvious in view of Sankaram, Applicants have amended independent claims 16 and 22 to delete "lipids" from the list of materials that can be used to form the microparticles. Applicants have also canceled dependent claims 18 and 54 in view of the amendment to independent claim 16. This amendment is made

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solely to expedite allowance of this application. Applicants reserve the right to pursue to canceled subject matter in a subsequently filed continuation application.

Claim Objections

Claims 19 and 20 were objected to for depending from a rejected claim. Applicants respectfully traverse this objection to the extent that it is applied to the claims as amended.

As noted above, independent claim 16 has been amended to delete "lipids" from the list of materials used to form the microparticles solely to expedite allowance of this application.

Claims 19 and 20 depend from claim 16. Therefore claims 19 and 20 should be in condition for allowance.

Allowance of claims 16, 19, 20, 22-27, 31, 32, and 36-53, as amended, is respectfully solicited.

Respectfully submitted,

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